



## General

### Guideline Title

Guidelines for improving entry into and retention in care and antiretroviral adherence for persons with HIV: evidence-based recommendations from an International Association of Physicians in AIDS Care panel.

### Bibliographic Source(s)

Thompson MA, Mugavero MJ, Amico KR, Cargill VA, Chang LW, Gross R, Orrell C, Altice FL, Bangsberg DR, Bartlett JG, Beckwith CG, Dowshen N, Gordon CM, Horn T, Kumar P, Scott JD, Stirratt MJ, Remien RH, Simoni JM, Nachega JB. Guidelines for improving entry into and retention in care and antiretroviral adherence for persons with HIV: evidence-based recommendations from an International Association of Physicians in AIDS Care panel. *Ann Intern Med.* 2012 Jun 5;156(11):817-33. [260 references] [PubMed](#)

### Guideline Status

This is the current release on the guideline.

## Regulatory Alert

### FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines](#) : A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.
- [March 22, 2016 – Opioid pain medicines](#) : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

## Recommendations

### Major Recommendations

The strength of recommendation (A-C) and quality of evidence (I-V) grading scales are defined at the end of the "Major Recommendations" field.

## Entry into and Retention in Human Immunodeficiency Virus (HIV) Medical Care

The associations between entry into and retention in HIV medical care and both individual health outcomes and HIV transmission dynamics mediated by antiretroviral therapy (ART) have been well-established in retrospective, prospective, and mathematical modeling studies. Accordingly, individual-level monitoring of entry and retention is essential to the development and evaluation of cost-effective interventions required to improve these critical components of clinical care.

*Recommendation 1:* Systematic monitoring of successful entry into HIV care is recommended for all individuals diagnosed with HIV (*II A*).

*Recommendation 2:* Systematic monitoring of retention in HIV care is recommended for all patients (*II A*).

*Recommendation 3:* Brief, strengths-based case management for individuals with a new HIV diagnosis is recommended (*II B*).

*Recommendation 4:* Intensive outreach for individuals not engaged in medical care within 6 months of a new HIV diagnosis may be considered (*III C*).

*Recommendation 5:* Use of peer or paraprofessional patient navigators may be considered (*III C*).

## Monitoring ART Adherence

Monitoring adherence is necessary to assess the effect of interventions and also to inform providers of the need to implement interventions. Measurement methods include self-reports, pharmacy refill data, pill counts, electronic drug monitors (EDMs), and drug concentrations from biological samples; each has unique strengths and weaknesses. Many of the studies reviewed combined measures to improve sensitivity and specificity, but because of the large variability in these approaches, these guidelines will not address these potential combinations here. Regardless of measurement method, adherence is a factor that varies with time and therefore must be repeatedly assessed.

*Recommendation 6:* Self-reported adherence should be obtained routinely in all patients (*II A*).

*Recommendation 7:* Pharmacy refill data are recommended for adherence monitoring when medication refills are not automatically sent to patients (*II B*).

*Recommendation 8:* Drug concentrations in biological samples are not routinely recommended (*III C*).

*Recommendation 9:* Pill counts performed by staff or patients are not routinely recommended (*III C*).

*Recommendation 10:* EDMs are not routinely recommended for clinical use (*I C*).

## Interventions to Improve ART Adherence

### ART Strategies

Important determinants of ART adherence and the related construct of ART persistence, or uninterrupted receipt of treatment, include dosing schedule, pill count, tolerability, and toxicity profiles of ART. Advances in ART now allow simplification of dosing schedules and reduction of pill burden for a majority of patients while maintaining excellent viral suppression. Additional factors to be considered in initiating or changing ART include transmitted or emergent viral resistance, individual ART treatment history, medical and psychosocial comorbid conditions, concomitant medications, and patient preference.

*Recommendation 11:* Among regimens of similar efficacy and tolerability, once-daily regimens are recommended for treatment-naïve patients beginning ART (*II B*).

*Recommendation 12:* Switching treatment-experienced patients receiving complex or poorly tolerated regimens to once-daily regimens is recommended, given regimens with equivalent efficacy (*III B*).

*Recommendation 13:* Among regimens of equal efficacy and safety, fixed-dose combinations are recommended to decrease pill burden (*III B*).

### Adherence Tools for Patients

Many commonly used self-management adherence tools, including pillboxes and medication planners or calendars, have been associated with improved adherence and HIV-1 ribonucleic acid (RNA) suppression. It is common for adherence tools to be combined with behavioral and structural interventions. Given their simplicity and observational data supporting their use, they are considered the standard of care despite limited comparative research to establish efficacy. Recommendations regarding use of these tools are limited because of this lack of evidence.

*Recommendation 14:* Reminder devices and use of communication technologies with an interactive component are recommended (*I B*).

*Recommendation 15:* Education and counseling using specific adherence-related tools is recommended (*I A*).

### Education and Counseling Interventions

Several systematic syntheses of behavioral interventions targeting ART adherence are available and report generally positive modest effect sizes, but the effect on HIV-1 RNA is less consistent. Recommendations are limited to those appropriate for general clinic populations; interventions targeting behavioral determinants of adherence in specific subgroups are included in other sections. Because of the volume and breadth of data supporting these recommendations, individual study results are not reviewed in detail, but Appendix Table 2 in the original guideline document describes studies and outcomes. Across recommendations, pertinent issues exist with regard to best structure, deliverer, training, duration, timing, frequency, and targets of educational and counseling interventions, as well as optimal modalities for dissemination and implementation.

*Recommendation 16:* Individual one-on-one ART education is recommended (*II A*).

*Recommendation 17:* Providing one-on-one adherence support to patients through one or more adherence counseling approaches is recommended (*II A*).

*Recommendation 18:* Group education and group counseling are recommended; however, the type of group format, content, and implementation cannot be specified on the basis of the currently available evidence (*II C*).

*Recommendation 19:* Multidisciplinary education and counseling intervention approaches are recommended (*III B*).

*Recommendation 20:* Offering peer support may be considered (*III C*).

### Health System and Service Delivery Interventions

The authors focused on interventions targeting factors believed to be related to adherence and ones that are also associated with systems of care or service delivery (for example, transportation to clinic and food supplements, staffing and service modifications, co-location of services) or influence social determinants, such as HIV-associated stigma.

*Recommendation 21:* Using nurse- or community counselor-based care has adherence and biological outcomes similar to those of doctor- or clinic counselor-based care and is recommended in under resourced settings (*II B*).

*Recommendation 22:* Interventions providing case management services and resources to address food insecurity, housing, and transportation needs are recommended (*III B*).

*Recommendation 23:* Integration of medication management services into pharmacy systems may be considered (*III C*).

*Recommendation 24:* Directly administered ART is not recommended for routine clinical care settings (*I A*).

### Special Populations

#### Pregnant Women

More than 50% of the 37.2 million adults with HIV in the world are women, and most are of childbearing age. Optimal ART adherence during pregnancy and the postpartum period remains a challenge globally. The evidence regarding ART adherence interventions during pregnancy comes predominantly from resource-limited settings and is focused only on short-term prevention of mother-to-child transmission (PMTCT) rather than on ART adherence throughout pregnancy and afterward.

*Recommendation 25:* Targeted prevention of mother-to-child transmission (PMTCT) treatment (including HIV testing and serostatus awareness) improves adherence to ART for PMTCT and is recommended compared with an untargeted approach (treatment without HIV testing) in high HIV prevalence settings (*III B*).

*Recommendation 26:* Labor ward-based PMTCT adherence services are recommended for women who are not receiving ART before labor (*II B*).

#### Substance Use Disorders

Individuals with alcohol and other substance use disorders are at increased risk for poor retention in care, poor adherence, and virologic failure. Several adherence strategies not recommended for general clinic populations are effective among those with substance use disorders.

*Recommendation 27:* Offering buprenorphine or methadone to opioid-dependent patients is recommended (II A).

*Recommendation 28:* Directly administered ART (DAART) is recommended for individuals with substance use disorders (I B).

*Recommendation 29:* Integration of DAART into methadone maintenance treatment for opioid-dependent patients is recommended (II B).

## Mental Health

Mental health disorders may predispose individuals to acquiring HIV, are common among individuals living with HIV, and present serious challenges for HIV treatment adherence. A meta-analysis of 95 studies found a significant relationship between depression and ART nonadherence that was consistent across patients in resource-rich and resource-limited settings. Research has linked depressive symptoms to poor HIV care engagement and health outcomes, including impaired immunologic response and mortality.

*Recommendation 30:* Screening, management, and treatment for depression and other mental illnesses in combination with adherence counseling are recommended (II A).

## Incarceration

HIV and acquired immune deficiency syndrome (AIDS) prevalence is higher among incarcerated populations in low-, middle-, and high-income countries. Globally, incarceration negatively affects continuity of care; development of trust; and, ultimately, optimal adherence. Incarceration provides a public health opportunity to provide ART to HIV-infected persons; however, barriers to ART delivery and adherence exist, and unintended ART interruptions sometimes occur after release. Key challenges to ART adherence among criminal justice populations include identifying successful strategies for medication distribution that preserve confidentiality and avoid stigma and maintaining persistent ART use during transitions from correctional facilities to the community.

*Recommendation 31:* DAART is recommended during incarceration (III B) and may be considered upon release to the community (II C).

## Homeless and Marginally Housed Individuals

In communities where stable housing is a societal norm, homeless persons represent a special population with respect to ART adherence because of the multiple and often interrelated adherence challenges in this population (such as unstable housing, mental illness, substance use disorders, food insecurity, mistrust of the health care system, incarceration, and inconsistent provider–patient relationships). Homelessness itself often disrupts daily routines, including medication taking, and can make medication storage difficult. In highly resourced countries, many homeless people have concomitant mental illness or substance use disorders that are associated with incomplete adherence. Mistrust of the health system and inconsistent provider–patient relationships can contribute to delayed entry into care. The homeless have competing survival needs, including food access, which have been associated with incomplete adherence and poor viral suppression. Excellent adherence and reliable viral suppression can, however, be achieved despite these multiple barriers.

*Recommendation 32:* Case management is recommended to mitigate multiple adherence barriers in the homeless (III B).

*Recommendation 33:* Pillbox organizers are recommended for persons who are homeless (II A).

## Children and Adolescents

HIV-infected young people between birth and 24 years of age are a developmentally diverse group, including those perinatally and behaviorally infected. For perinatally infected children, adherence to medications is determined largely by their caregivers, who often have many challenges, including HIV infection. Unique medication-related factors associated with nonadherence for children include difficulty swallowing pills, bad taste of medications, and difficulty timing medication administration around meals. Perinatally infected teens often experience deterioration in medication adherence during adolescence, as do their peers with other chronic diseases. Transition from pediatric to adult care settings may create additional adherence barriers because of disruptions in comprehensive services and insurance issues. Adolescents and young adults are less likely than their older counterparts to be retained in care and receive prescriptions for ART, and they have worse clinical outcomes.

*Recommendation 34:* Intensive youth-focused case management is recommended for adolescents and young adults living with HIV to improve entry into and retention in care (IV B).

*Recommendation 35:* Pediatric- and adolescent-focused therapeutic support interventions using problem-solving approaches and addressing psychosocial context are recommended (III B).

*Recommendation 36:* Pill-swallowing training is recommended and may be particularly helpful for younger patients (IV B).

*Recommendation 37:* DAART improves short-term treatment outcomes and may be considered in pediatric and adolescent patients (IV C).

## Definitions:

### Quality of the Body of Evidence

Quality	Interpretation
<b>Excellent (I)</b>	<ul style="list-style-type: none"><li>• Randomized controlled trial (RCT) evidence without important limitations</li><li>• Overwhelming evidence from observational studies</li></ul>
<b>High (II)</b>	<ul style="list-style-type: none"><li>• RCT evidence with important limitations</li><li>• Strong evidence from observational studies</li></ul>
<b>Medium (III)</b>	<ul style="list-style-type: none"><li>• RCT evidence with critical limitations</li><li>• Observational study evidence without important limitations</li></ul>
<b>Low (IV)</b>	<ul style="list-style-type: none"><li>• Observational study evidence with important or critical limitations</li></ul>

### Strength of Recommendations

Strength	Interpretation
<b>Strong (A)</b>	Almost all patients should receive the recommended course of action.
<b>Moderate (B)</b>	Most patients should receive the recommended course of action. However, other choices may be appropriate for some patients.
<b>Optional (C)</b>	There may be consideration for this recommendation on the basis of individual patient circumstances. Not recommended routinely.

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS)

### Guideline Category

Counseling

Evaluation

Management

Treatment

### Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Nursing

Obstetrics and Gynecology

## Intended Users

Advanced Practice Nurses

Health Care Providers

Health Plans

Managed Care Organizations

Nurses

Patients

Pharmacists

Physician Assistants

Physicians

Public Health Departments

Social Workers

Substance Use Disorders Treatment Providers

## Guideline Objective(s)

- To define best practices that can be used by practitioners and health systems to improve adherence and, in turn, health outcomes in patients with human immunodeficiency virus (HIV)
- To provide recommendations on interventions to improve entry into and retention in care and antiretroviral therapy (ART) adherence for people living with HIV, as well as methods to monitor these critical processes

## Target Population

People living with human immunodeficiency virus (HIV) infection

## Interventions and Practices Considered

1. Systematic monitoring of successful entry into and retention in human immunodeficiency virus (HIV) care
2. Brief, strengths-based case management for individuals with a new HIV diagnosis
3. Intensive outreach for individuals not engaged in medical care within 6 months of a new HIV diagnosis
4. Use of peer or paraprofessional patient navigators
5. Monitoring antiretroviral therapy (ART) adherence through self-reported adherence and pharmacy refill data
6. Measuring drug concentrations in biological samples (not routinely recommended)
7. Pill counts (not routinely recommended)
8. Electronic drug monitoring (not routinely recommended)
9. Use of once-daily ART regimens and fixed-dose combinations to decrease pill burden
10. Use of reminder devices and communication technologies with an interactive component
11. Education and counseling using specific adherence-related tools
12. Individual one-on-one ART education

13. Providing one-on-one adherence support to patients through one or more adherence counseling approaches
14. Group education and group counseling
15. Multidisciplinary education and counseling intervention approaches
16. Offering peer support
17. Using nurse- or community counselor-based care
18. Interventions providing case management services and resources to address food insecurity, housing, and transportation needs
19. Integration of medication management services into pharmacy systems
20. Targeted prevention of mother-to-child transmission (PMTCT) treatment, including HIV testing and serostatus awareness and labor ward-based PMTCT adherence services
21. Offering buprenorphine or methadone to opioid-dependent patients
22. Directly administered ART (DAART) for individuals with substance use disorders and integration of DAART into methadone maintenance treatment
23. Screening, management, and treatment for depression and other mental illnesses in combination with adherence counseling
24. DAART during incarceration and upon release of incarcerated populations into the community
25. Case management and pillbox organizers to mitigate multiple adherence barriers in the homeless
26. Intensive youth-focused case management for children and adolescents
27. Pediatric- and adolescent-focused therapeutic support interventions
28. Pill-swallowing training for children
29. DAART for children and adolescents

## Major Outcomes Considered

- Mortality
- Morbidity
- Virologic failure
- Immunologic response
- Development of human immunodeficiency virus (HIV) resistance
- Adherence behaviors (as measured by self-report, pill count, electronic drug monitor, pharmacy refill, and other methods)
- Entry into and retention in care behaviors (such as clinic attendance and loss to follow-up)
- Adverse events

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Literature Search

#### *Interventions*

The following were the interventions of interest: 1) any intervention for improving entry into and retention in care for people with human immunodeficiency virus (HIV) and 2) any intervention for improving adherence to antiretroviral therapy (ART). The objective of the literature search was to identify optimal interventions for improving entry into and retention in care and ART adherence to assist with developing guidelines.

To be included, the studies had to meet the following criteria: 1) evaluated an intervention intended to improve entry into and retention in care or ART adherence; 2) had a randomized, controlled trials (RCTs) or observational design that included comparators (if sufficient RCT-level evidence for an intervention was available, then observational studies were not considered in the body of evidence); and 3) reported 1 or more relevant outcomes assessed after the intervention was completed (biological or behavioral). The following were exclusion criteria: observational studies

without comparators, letters, and editorials.

The study participants were children, adolescents, and adults with HIV. The included studies had the following biological and behavioral outcomes of interest: mortality, morbidity, virologic failure, immunologic response, development of HIV resistance, adherence behaviors (as measured by self-report, pill count, electronic drug monitor, pharmacy refill, and other methods), entry into and retention in care behaviors (such as clinic attendance and loss to follow-up), and adverse events.

### *Identification of Studies*

The search largely consisted of a systematic search performed on the Centers for Disease Control and Prevention (CDC) Prevention Research Synthesis Project Database, with some specific adaptations for this project. Since 1996, the CDC Prevention Research Synthesis Project has been conducting ongoing systematic searches of the HIV prevention intervention literature, focusing on HIV risk reduction and medication adherence, to establish a cumulative, comprehensive research database for conducting regular systematic reviews. This database has been developed and updated by annual automated electronic database searches, quarterly hand searches of journals, and daily ad hoc searches of the published literature from 1988 to the present. The database created for these guidelines began with pertinent evidence from 1996 and included the most recent annual electronic search of the CDC database (February 2011), hand searching through March 2011, and additional ad hoc searching through November 2011. The searches were performed with no limits for language, setting, or age. The evidence base for these guidelines was restricted to RCTs and observational studies with comparators that had at least 1 measured biological or behavioral end point.

The panel searched the following journal databases: MEDLINE, EMBASE, PsycINFO, CINAHL, and AIDSLINE (before retirement in 2000). The following conference databases were searched from July 2009 to June 2011: Conference on Retroviruses and Opportunistic Infections; IAPAC Adherence Conference; International AIDS Conference; and the International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention.

The clinical trials databases searched were CENTRAL (Cochrane Central Register of Controlled Trials), ClinicalTrials.gov (<http://clinicaltrials.gov>), Current Controlled Trials ([www.controlled-trials.com](http://www.controlled-trials.com)), and Pan-African Clinical Trials Registry ([www.pactr.org](http://www.pactr.org)).

Sixteen journals that typically contribute the most relevant citations were also hand-searched for medication adherence and retention studies. The authors contacted individual researchers and members of relevant organizations working in the field, including panel members, to identify studies and completed or ongoing trials.

The authors checked the reference lists of all studies identified by the preceding methods and examined the bibliographies of any relevant systematic reviews, meta-analyses, or current guidelines the authors identified during the search process.

### *Monitoring*

In addition to producing evidence-based guidelines for entry into care, retention in care, and ART adherence interventions, the panel also targeted the identification of strategies and methods for adherence monitoring or assessment, which required separate methods to search, grade, and synthesize evidence. The resulting list of articles was reviewed to include only studies that compared an adherence measurement method with a biological outcome.

### *Study Inclusion Criteria*

The studies must have included one or more methods of adherence measurement and compared clinical or biological outcomes (as listed above).

### *Search Strategy*

Keyword searches (*monitoring, measure*) were performed on the original database to identify articles specific to HIV monitoring. One panel member reviewed citations found from keyword searches to determine whether they met inclusion criteria. In addition, all articles initially identified as potential intervention articles were screened to see whether they were also of relevance to HIV monitoring. Supplementary searching for relevant articles was also performed as described above.

## Number of Source Documents

A total of 325 studies were identified for inclusion in the evidence base for the guidelines.



# Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Quality of the Body of Evidence

Quality	Interpretation
<b>Excellent (I)</b>	<ul style="list-style-type: none"><li>• Randomized controlled trial (RCT) evidence without important limitations</li><li>• Overwhelming evidence from observational studies</li></ul>
<b>High (II)</b>	<ul style="list-style-type: none"><li>• RCT evidence with important limitations</li><li>• Strong evidence from observational studies</li></ul>
<b>Medium (III)</b>	<ul style="list-style-type: none"><li>• RCT evidence with critical limitations</li><li>• Observational study evidence without important limitations</li></ul>
<b>Low (IV)</b>	<ul style="list-style-type: none"><li>• Observational study evidence with important or critical limitations</li></ul>

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

### Data Abstraction and Grading

Articles identified for inclusion were abstracted (for example, study title, date, measures used, and estimates of association) and graded by using a modified Quality Assessment for Diagnostic Accuracy Studies (QUADAS) tool.

### Evidence Synthesis Strategy

Data on measures from the studies were compiled into summary tables listing ranges of association, quality ratings, and other factors. Quality of the body of evidence and strength of recommendation were then rated according to the methods detailed below.

### Individual Study Evaluation Methods

#### Data Extraction and Management

After the initial search and article screening, 2 reviewers independently coded and entered information from the included studies onto a standardized data extraction form; differences were resolved by consensus with a third reviewer. Extracted information included the following: study details (citation, start and end dates, location, study design); participant details (study population, ages, population size); interventions details (duration, nature, and intensity of the intervention); and outcome details (mortality, clinical disease progression [AIDS and non-AIDS events], treatment response [CD4 recovery and viral load response], adherence, retention, loss to follow-up, resistance, and adverse events). These data were then summarized in a table.

#### Assessment of Risk for Bias in Included Studies

The 2 reviewers then assessed each study for risk for bias; differences were resolved by consensus with a third reviewer. The results were summarized in tables. The Cochrane Risk of Bias Tool was used for randomized controlled trials (RCTs). This tool assesses risk for bias in individual studies across 6 domains with 3 potential responses for each domain: yes, no, or unclear.

Reviewers assessed observational studies for risk for bias by using the Newcastle-Ottawa Quality Assessment Scale. This validated scale assesses quality of cohort and case-control studies in 3 main areas by using a "star rating system" ranging from 0 to 9.

## Methods Used to Formulate the Recommendations

### Expert Consensus

## Description of Methods Used to Formulate the Recommendations

The International Association of Physicians in AIDS Care (IAPAC) convened a panel of 31 members, consisting of experts in clinical care, clinical trials, behavioral science, pharmacy, and guideline methods and patient representatives. From this panel, 20 members volunteered to be on the writing team. The panel determined the issues to be covered on the basis of a systematic literature review and developed these guidelines using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument for practice guideline assessment. This process was conducted in accordance with Institute of Medicine Standards for Developing Trustworthy Clinical Practice Guidelines.

After each individual study was evaluated, panel members proposed draft recommendation statements based on the evidence gathered and concurrently grouped individual studies together to form the body of evidence for each specific recommendation. The body of evidence for each recommendation was then evaluated according to the factors listed in the table below.

### Process for Evaluating the Body of Evidence

Factor	Decreases or Increases Quality	Comment
Study limitations	Decrease	As indicated by individual study evaluation tools
Inconsistency of results	Decrease	Widely differing estimates in treatment effect (i.e., heterogeneity)
Indirectness of evidence	Decrease	Evidence does not directly address relevant population or intervention(s) not directly compared
Imprecision	Decrease	Small sample sizes or events with wide confidence intervals (CIs)
Publication bias	Decrease	Evidence of publication bias found in the systematic review
Large magnitude of effect	Increase	Large or very large estimates of effect increase confidence in results
Dose response	Increase	Evidence for dose-response relationship increases plausibility
Plausible confounding would change the effect	Increase	All plausible confounding would reduce the demonstrated effect or increase the effect if no effect was observed

All of these factors were considered in decreasing or increasing the quality of the body of evidence and were framed around the standards and interpretation listed (see the "Rating Scheme for the Strength of the Evidence" field). Panel members then decided on a grade and, using standardized forms, detailed instances if and why they increased or decreased the quality of the body of evidence, specifically referencing the factor(s) involved.

### Moving From Evidence to Recommendation

After recommendation statements had been proposed and the corresponding body of evidence for each recommendation graded, the factors listed in the table below in were considered to determine the strength of the recommendation.

### Factors Considered in Determining the Strength of the Recommendation

Factor	Comment
Quality of the body of evidence	The higher the quality of evidence, the stronger the recommendation.
Magnitude of benefit	The larger the benefits, the stronger the recommendation.
Magnitude of risks and burdens	The smaller the risks and burdens, the stronger the recommendation.
Costs	The lower the costs, the stronger the recommendation.

Factor	Comment
Values and preferences	Key patient and provider values and preferences.

Each of the factors was explicitly considered. Panel members then decided on a strength of recommendation and, using standardized forms, detailed how they came to this decision, specifically referencing each factor as appropriate. Note that quality of the body of evidence was only 1 factor considered in the strength of recommendation.

## Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Strength	Interpretation
Strong (A)	Almost all patients should receive the recommended course of action.
Moderate (B)	Most patients should receive the recommended course of action. However, other choices may be appropriate for some patients.
Optional (C)	There may be consideration for this recommendation on the basis of individual patient circumstances. Not recommended routinely.

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

## Description of Method of Guideline Validation

An international group of content experts reviewed a draft of these guidelines, and relevant modifications were made to the manuscript. Guideline panel members will review these guidelines periodically and make updates as new evidence becomes available.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Improved rates of entry into and retention in care and adherence to antiretroviral therapy regimens for persons with human immunodeficiency virus (HIV)

### Potential Harms

Adverse drug effects associated with antiretroviral therapy

# Qualifying Statements

## Qualifying Statements

These recommendations are based on the best published science; however, the evidence base remains insufficient in many areas. For that reason, the authors also highlight areas in which additional research is needed to inform future recommendations. The authors realize that implementation of these recommendations may, in some cases, require that new resources be identified to bring the benefit of best practices to clinic populations. The authors believe that presenting recommendations based on rigorous science is the best avenue to achieve that end.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Foreign Language Translations

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Living with Illness

Staying Healthy

### IOM Domain

Effectiveness

Timeliness

## Identifying Information and Availability

### Bibliographic Source(s)

Thompson MA, Mugavero MJ, Amico KR, Cargill VA, Chang LW, Gross R, Orrell C, Altice FL, Bangsberg DR, Bartlett JG, Beckwith CG, Dowshen N, Gordon CM, Horn T, Kumar P, Scott JD, Stirratt MJ, Remien RH, Simoni JM, Nachega JB. Guidelines for improving entry into and retention in care and antiretroviral adherence for persons with HIV: evidence-based recommendations from an International Association of

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2012 Jun 5

## Guideline Developer(s)

International Association of Providers of AIDS Care - Professional Association

## Source(s) of Funding

Development of the guidelines was jointly sponsored by the International Association of Physicians in AIDS Care (IAPAC) and the U.S. National Institutes of Health's Office of AIDS Research.

## Guideline Committee

International Association of Physicians in AIDS Care Guidelines Panel

## Composition of Group That Authored the Guideline

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## Financial Disclosures/Conflicts of Interest

Each member completed a written conflict-of-interest disclosure. All potential conflicts of interest were declared, discussed, and resolved by the panel. Disclosures from authors and panel members can be viewed at <https://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M12-0061> .

## Guideline Status

This is the current release on the guideline.

## Guideline Availability

Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from International Association of Physicians in AIDS Care, 1640 Rhode Island Avenue NW, Suite 200, Washington, DC 20036; e-mail, [iapac@iapac.org](mailto:iapac@iapac.org).

## Availability of Companion Documents

The following are available:

- Guidelines for improving entry into and retention in care and antiretroviral adherence for persons with HIV. Evidence-based recommendations from an IAPAC panel. Summary of recommendations. Washington (DC): International Association of Physicians in AIDS Care; 2012. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the [International Association of Physicians in AIDS Care \(IAPAC\) Web site](#) .
- Guidelines for improving entry into and retention in care and antiretroviral adherence for persons with HIV. Slide set. AIDS Education and Training Center (AETC) National Resource Center. 2012 May. 29 slides. Electronic copies: Available in English and Spanish from the [AETC Web site](#) .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on July 16, 2012. The information was verified by the guideline developer on August 8, 2012. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines.

## Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

## Disclaimer

### NGC Disclaimer

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